



Instructions for use

General information

Manufacturer information



Mitral

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Website: <https://www.apneal.ai/>

Device information



Apneal Pro is a class IIa medical device in accordance with Regulation (EU) 2017/745 (for Medical Device Regulation). The CE marking is placed on the device via the application interface in the '**About**' screen in the settings.



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1. Definition and glossary

Term	Definition
AHI	Apnea-Hypopnea Index Average number of apneas and hypopneas during the night per hour of sleep. The AHI quantifies the severity of sleep apnea-hypopnea syndrome and is expressed as events per hour of sleep.
Respiratory events	Apneas are defined as complete ($\geq 90\%$) cessations of airflow lasting at least 10 seconds. Hypopneas are defined, in accordance with the American Academy of Sleep Medicine (AASM) 2023 Scoring Manual, as a $\geq 30\%$ reduction in airflow lasting at least 10 seconds, associated with either a $\geq 3\%$ oxygen desaturation or an arousal from sleep.
Obstructive apnea or hypopnea	Sleep-related respiratory events characterized by repeated episodes of complete or partial upper airway obstruction during sleep.
Central apnea or hypopnea	Sleep-related respiratory events characterized by repeated episodes of absent or significantly reduced respiratory effort during sleep, resulting in reduced airflow without upper airway obstruction.
Indeterminate apnea or hypopnea	Sleep-related respiratory events that cannot be clearly classified as obstructive or central due to limited or inconclusive data.
min	Minutes
dB	Decibel: Unit of measurement of sound intensity.
bpm	Beats per minute: Unit of measurement of Heart Rate (HR) Number of heartbeats (or pulses) occurring in one minute.
HR	Heart rate
PSG	Polysomnography

2. Product description

2.1 Intended use

Apneal Pro is a Software as a Medical Device intended for use on a smartphone, designed to measure physical and physiological sleep parameters with the aim of screening and aiding in the diagnosis of Sleep Apnea Hypopnea Syndrome (SAHS) in adult patients with sleep complaints



Apneal is not intended as a replacement for full polysomnography when additional parameters are needed.

2.2 Technical performance and benefit

The technical performance of the Apneal Pro has been validated and compared with the gold-standard polysomnography (PSG) in 432 adult patients.

Apnea-Hypopnea Index (AHI) measured by Apneal presents:

- A Pearson correlation > 85% with the AHI extracted from the PSG
- An average difference with the AHI extracted from the PSG inferior to 5 e/h with a standard deviation of the differences inferior to 10 e/h
- An average of the absolute difference with the AHI extracted from the PSG inferior to 10 e/h with a standard deviation of the differences inferior to 10 e/h
- Sensitivity and specificity for classifying 4 classes of AHI
 - normal (AHI <5)
 - mild ($5 \leq \text{AHI} < 15$)
 - moderate ($15 \leq \text{AHI} < 30$) and
 - severe ($\text{AHI} \geq 30$)

According to the following 3 thresholds:

	Sensitivity (Se)	Specificity (Sp)
AHI > 5	> 0,9	> 0,7
AHI > 15	> 0,8	> 0,8
AHI > 30	> 0,75	> 0,9

NOTE: The Apnea-Hypopnea Index (AHI) was scored strictly following the standardized clinical criteria recommended by the AASM 2023 Scoring Manual. It was calculated without any threshold optimization. No data-driven or machine-learning-based threshold tuning or adjustment was applied. According to the AASM, the AHI is defined as the total number of apneas and hypopneas per hour of sleep.



Total Sleep Time (TST) measured by Apneal presents:

- An average difference with the TST extracted from the polysomnography (PSG) inferior to 11 minutes with a standard deviation of the differences inferior to 55 minutes.
- An average of the absolute difference with the TST extracted from the polysomnography (PSG) inferior to 40 minutes with a standard deviation of the differences inferior to 45 minutes.

Other variables of interest measured by Apneal present the following results:

Body position: The body position detection method demonstrated an overall agreement greater than 0.95 with the PSG video reference across supine, prone, and lateral positions.

Snoring detection: The snoring detection method demonstrated sensitivity greater than 0.90 in identifying snoring events compared with PSG ambient-microphone annotations.

Heart rate: The heart rate method demonstrated a mean absolute difference of less than 2 beats per minute compared with the electrocardiogram reference when evaluated over 5-second averaging periods.

Central Apnea Index (CAI): The measured CAI showed an intraclass correlation coefficient greater than 0.90 relative to the PSG CAI.

This device is intended to provide an indirect clinical benefit by:

- Reducing SAHS diagnostic delays and
- Enabling faster referral to a sleep specialist.

2.3 Functional description

To measure physiological parameters during sleep, the device records noise and movement via sensors embedded in your smartphone (accelerometer, microphone, and gyroscope) and sensors placed on your chest.

This data, combined with your personal data (such as gender, age, and answers to sleeping questionnaires), is analyzed by our dedicated proprietary software.

The smartphone application allows you to:

- Log in securely and enter user data,
- Complete your sleep test using only your smartphone's sensors
- Analyze the sleep data collected during the night
- Display and download your sleep reports

3. Safety information

3.1 Contraindications and/or undesirable effects



Contraindication: Do not use it in patients with **active implantable medical devices** (e.g., pacemakers, mechanical heart valves, electrical neurostimulators...)

3.2 General precautions and warnings

Please read this section carefully before using the device, ensuring you understand it and can use the device according to the instructions.



Apneal Pro provides an automated analysis to aid diagnosis. Clinical judgment by a qualified healthcare professional is required — do not rely solely on Apneal Pro results to self-diagnose or to make definitive diagnostic or treatment decisions. Failure to follow this warning may result in delayed or missed diagnosis of a serious medical condition.

Limitations of use

The safety and performance of Apneal have not been established under the following conditions or in the following patient populations. Use of the device in these situations is outside the clinically validated conditions of use and may affect the reliability or clinical relevance of the results:

- Patient with thoracic deformities or atypical thoracic movements preventing proper positioning of the phone on the chest
- Patient suffering from neurological disorders causing involuntary or uncontrollable movements
- Patients with moderate or severe valvular disease.
- CPAP therapy titration
- Pregnant women
- Children (<18yo)

3.3 Reporting incidents and information to a healthcare professional

Reporting serious incidents

If you experience any unexpected problems while using this device — especially anything that could cause or cause harm — stop using it and seek medical advice. Please report it to us at support@apneal.ai.

Include, if possible:



- Your contact details,
- The software name and version (shown in the app/menu)
- What happened, when it happened, and any error messages or screenshots
- Whether you needed medical help

You must also report the incident to your national health authority (medical device competent authority) in your country.

Consulting a health professional

If you experience worsening symptoms (fatigue, snoring) or do not understand the information provided by the device, it is advisable to consult a qualified healthcare professional for medical advice and, if necessary, undergo a diagnostic evaluation (such as polysomnography).

3.4 Paper version

A paper version of this document is available upon request within 7 days with no additional cost. Please email support@apneal.ai to request it.

3.5 Security and safe use at home

- Use the phone you usually use; keep the phone's operating system up to date before recording.
- Do not allow others to use the phone or app while a recording is in progress.
- If the app displays an update message, follow the in-app instructions or contact support before the next recording.



If you suspect a cybersecurity incident (unexpected behavior, unauthorized access, data breach or ransomware) affecting Apneal, stop using the device immediately if doing so is safe, isolate it from networks where possible, and contact the manufacturer's support: support@apneal.ai.

3.6 Privacy and data information

We use only the minimum personal data necessary for the device's safety, performance, and support, in accordance with Regulation (EU) 2017/745 and applicable data protection laws (e.g., GDPR). We also apply appropriate security measures and respect your rights (access, rectification, erasure). For details about what we collect, how long we keep it, who can see it, and how to exercise your rights (access, rectification, deletion, restriction, portability, complaint to the Data Protection Authority), see our Privacy Notice or contact us.

4. How to use

4.1 Installation of the software and required configuration

Installation: Smartphones can be installed by anyone using the Google Play application or the App Store.

Supported OS: iOS ≥ 14 and Android ≥ 8.0 with the latest security patches.

Hardware: Minimum 1 gigabyte of free storage to start recording.



Device compatibility



Apneal Pro requires a smartphone with the following sensors:

- microphone,
- accelerometer, and
- gyroscope;

If any of these sensors are missing, unsupported, or disabled, the app will not function correctly and the 'Start a night' feature **will be unavailable**.

Consumables

The following consumables are required to adjust and maintain your smartphone in the correct position throughout the night.

Items	Description	Reference
Adhesive strip	One single-use adhesive strip (approx. 25 cm in length). Used to secure the smartphone on the chest.	 Fleming Medical UR68 Urgoderm Wide Area Fixation Dressing, 10cm x 10m - Walgreens Non-Stick Pads 2 In x 3 In
Cohesive bandages	Two long, cohesive elastic bandages, each long enough to wrap around the thorax. Used to maintain the smartphone and adhesive strip securely in place during the night.	 Boots Cohesive Support Bandage (7cm x 4m) - Pain free wrap (4 in x 2.2 yd) (CVS)



Use adhesive and cohesive tapes in accordance with the manufacturer's recommendations - Do not clean and do not re-use it



If you have known allergies to adhesives or elastic materials, do not use the device, as contact with these components may cause skin irritation or allergic reactions.

4.2 Start-up procedure

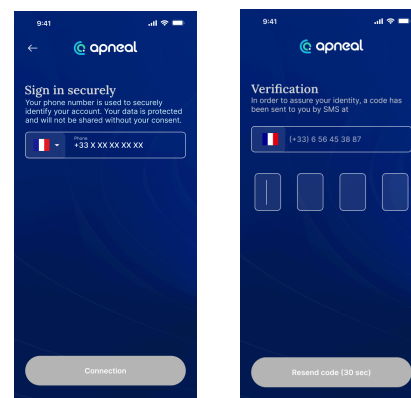
To get started, open the **Apneal Pro App** and swipe through the introduction screens. You'll arrive at the login screen, where you'll need to enter your credentials to sign in.

1. Identification

Enter your mobile phone number in the designated field. This number will be used to secure your account and simplify the login process.

2. Verification code (2FA)

A verification code will be sent to the phone number you entered. This code is required to confirm that the number is yours.



3. Account creation and activation

At this moment, in both cases, your phone number is automatically written.



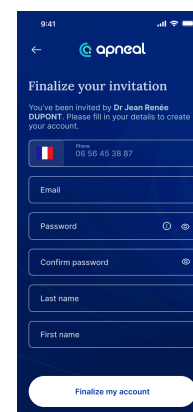
The Apneal Pro account is for one user only and must not be shared.

Case 1: You have been invited

If you have received an invitation (for example, from your healthcare professional).

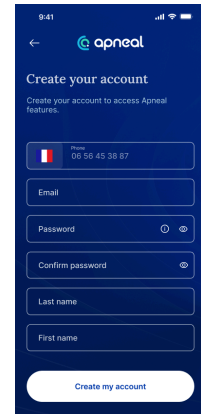
Here are the steps to follow:

- Enter the email address you used when you received the invitation, as well as your first and last name.
- Create a secure password
- Click on 'Create my account' to confirm.



Case 2: Self-registration

- Enter your email address, then your first and last name. (The phone number is populated automatically after authentication.)
- Create a secure password.
- Tap "Finalize my account".



Account consents

During account creation and finalization, users must accept all mandatory account consents before their account can be created or finalized. The mandatory consents include the Terms of Use, the Privacy Policy, and any additional required consents configured for the account.

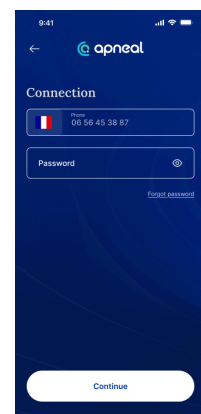
If any required consent is not accepted, the account cannot be created or finalized.

4. Login

If you have already created your account (whether invited or not), follow these steps to reconnect:

- Enter the phone number you used to create your account
- Enter your password
- Press the 'Sign in' button

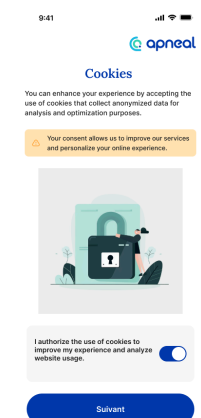
Forgot your password? → A recovery option is available.



5. Cookies consent

After your account has been created, a dedicated cookie consent page is displayed.

Accepting cookies is optional, but it enhances your experience by allowing us to analyze how the application is used. You can choose whether to accept or decline cookies according to your preferences.



6. Onboarding

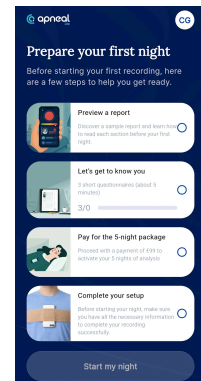
To complete your account setup and prepare for your sleep assessment, several features are available within the onboarding page.

Questionnaires

Three questionnaires are available to personalize your sleep profile:

- Your general information
- Your medical history
- Your sleep profile

The information you provide enables the application to better understand your needs and provide you with personalized recommendations.



Account activation

If your account has not yet been activated, you must complete the payment before you can proceed. You can activate your account by either:

- making the payment directly within the application, or
- using the Patient Portal through the invitation SMS you received. For more information, refer to section 4.11.1.

Tutorials

You can browse the onboarding slides explaining how to prepare your smartphone for the overnight recording. You can also access the video tutorials, which explain what equipment you will need before starting your sleep assessment and guide you through the installation process.

For more information, refer to section 4.3.

Report preview

A preview of the different sections of the sleep report is available to help you understand the results generated after your overnight recording.

For more information, refer to section 4.7.

4.3 Setting up the smartphone

Before starting the recording...



RISK OF ELECTRICAL SHOCK:

- Do not charge the smartphone while it is attached to your body.
- Do not use for sleep recording while the device is charging.
- Use the original manufacturer charger or certified equivalent. Do not use the device if the charger/cable is damaged.
- Keep the device dry — do not use in bath/shower.



DO NOT use a smartphone with a cracked or broken screen, as sharp glass may cause cuts or injuries; replace or repair the device before use.

Check battery level

To ensure the recording works, your smartphone must have a **battery level above 30%**. If your battery level is below this threshold, **please charge your phone before starting recording**.

A battery level of **60% or higher is strongly recommended** to guarantee smooth operation throughout the night. You won't be able to plug it in to charge it during the recording.

Ensure optimum sleep environment

Make sure you will be alone in the room, in a quiet, dark environment, with the windows closed and no disruptive ambient noise (fan, air conditioner, TV, etc.).

On some phones, heavy CPU use by other apps or system thermal management can cause recording interruptions. For best results:

- close other apps,
- disable power-intensive modes

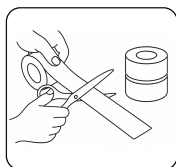
The app logs any interruptions; if an interruption occurs, you may be asked to repeat the recording at night



Step 1 - Verification of the required materials

Before starting the installation, make sure you have the following items:

- A pair of scissors
- A roll of adhesive tape
- A roll of cohesive tape



Step 2 - Preparation of the strips

- Cut a **25 cm adhesive strip**
- Cut **two long cohesive strips** (enough to go around your chest).

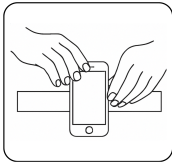
Step 3 - Launch the sleep recording

Before placing your phone on your chest, make sure to complete all the startup steps the app displays for night recording (set the start time, activate airplane mode, etc.).



Once the smartphone is secured with the adhesive tape (Step 4), it cannot be used for calls, messages, or other apps. It should only be used to perform the sleep assessment - Airplane Mode must be activated.

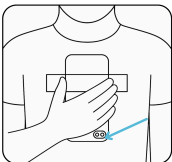
Make sure you will not need your phone before proceeding to the next installation step.



Step 4 - Prepare the smartphone with adhesive tape

Remove all accessories (such as bulky phone cases, cables, and headphones) that may hinder the smartphone from lying flat against the chest.

Once the recording has started, **peel off the protective** cover from the adhesive strip and **stick the back of the phone** onto the adhesive part.



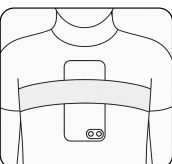
Step 5 - Positioning the phone on the chest

Place the phone against your chest, centered **two fingers below the collarbones**, and make sure that:

- The screen is facing your chest
- The camera is oriented **facing down**



Do not wear on bare skin – To avoid direct skin contact, place the smartphone over your nightwear (preferably thin clothing to optimize signal acquisition).



Step 6 - Stabilize with cohesive strips

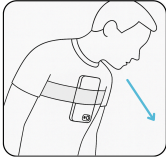
Reproduce this step with the 2 cohesive bands.

- Place the band horizontally across your back, at chest height, holding each end firmly in one hand.
- Pull the band tight, then bring each end forward one at a time and fold them over your chest.
- **Adjust the pressure around your thorax** to ensure a **good hold** of the phone.
- Finally, slide one end under the already wrapped band to secure it tightly and prevent it from coming loose.



RISK OF STRANGULATION

Do not place or route any band or strap around your neck



Step 7 - Positioning verification

Lean slightly forward to check that

- The phone is not moving and
- There is no gap between the phone and your chest

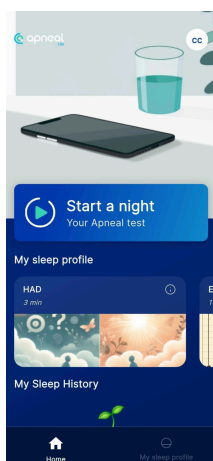


Do not overtighten – Adjust the cohesive bands if you feel discomfort due to excessive pressure to preserve your sleep quality.

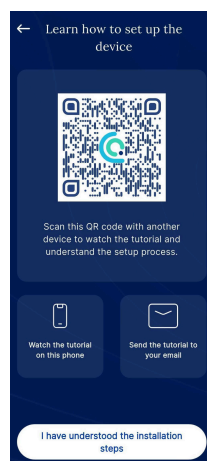
4.4 Operating instructions of the app

Starting the recording of your night

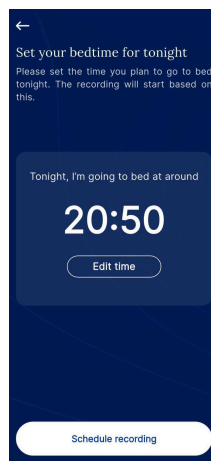
- 1 Click on Start a night.
- 2 Watch the tutorials to properly position the smartphone on your chest.
You can access it from:
 - The application itself
 - The QR code
 - The URL sent by email
- 3 Choose a start time.
- 4 Turn on airplane mode and turn off the wifi.
- 5 Place your phone on your chest as described in the tutorials.



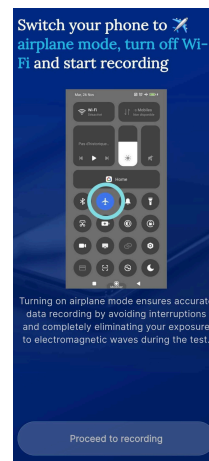
1



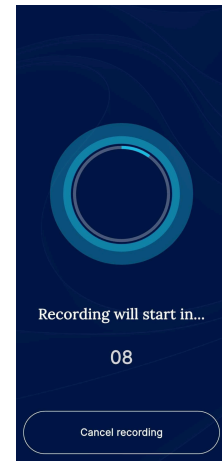
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3



4



5



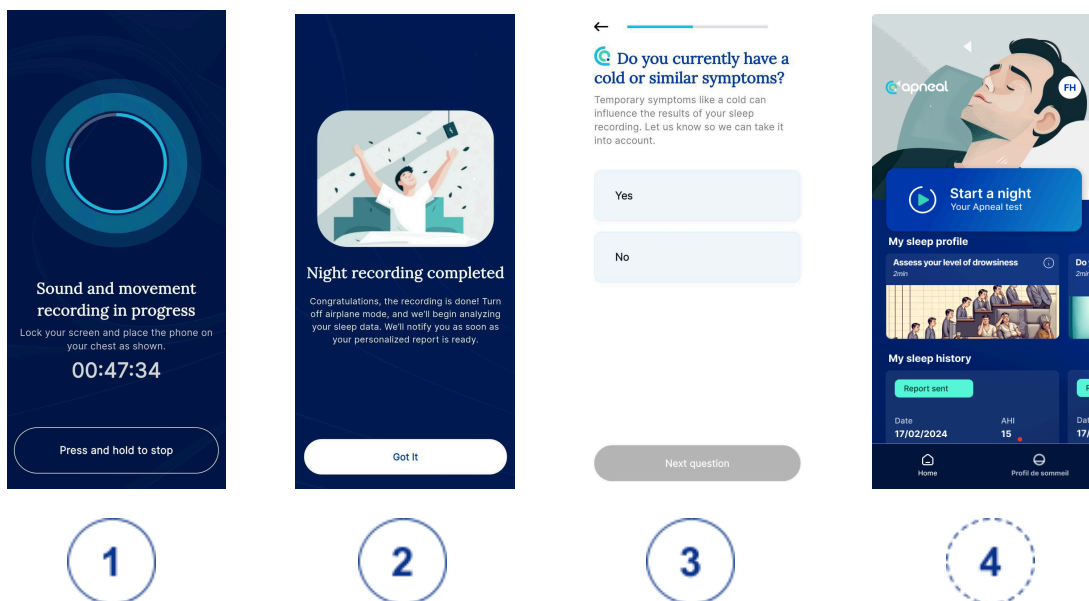
Do not force close the app from the start of the recording until the end of your night, as this will stop the recording. Press the "cancel recording" button instead.

4.5 Cancel the night

You can cancel the night by clicking the **"Cancel recording"** button on the page that displays the remaining time before your night recording starts.

4.6 End of recording & send for analysis

- 1 Upon waking, please stop the recording by holding the button for 3 seconds.
- 2 Turn off airplane mode and then press continue to send your recording to Apneal's secure server for analysis.
- 3 Take the questionnaire after you've finished your night.



Once you have submitted the questionnaire, you will be redirected to the main menu, where you can view your most recent nights.

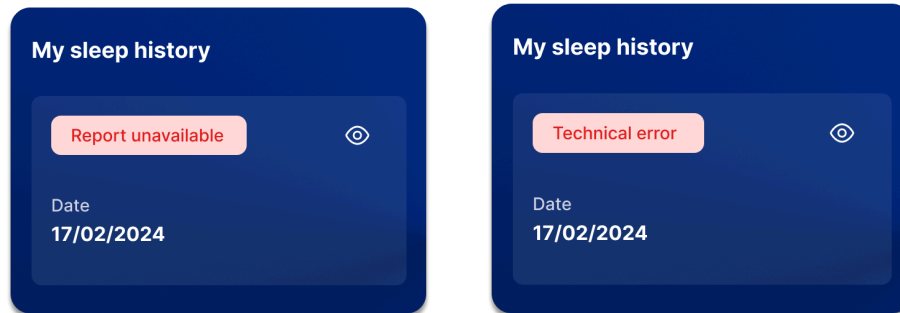
At the top of the box for your night, you will see your registration status.

If you have completed more than 4 nights, a 'View history' button will allow you to access your complete history.

4.7 Night Report Generation — Error Handling

If your sleep report cannot be generated after a recording, you will be **notified**.

The dashboard will display a card summarizing the status of the night session.



By clicking the eye icon on this card, you can access a detailed view describing the cause of the issue and the appropriate corrective action.

Case 1: Insufficient or invalid data

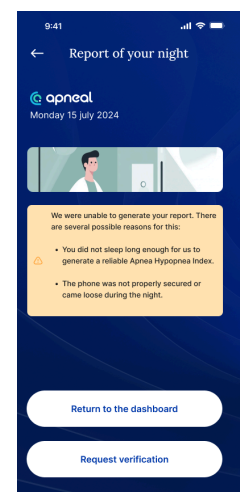
In this case, the report status will appear as "Report unavailable."

The application was unable to generate a reliable Apnea–Hypopnea Index due to insufficient data.

Possible reasons include:

- The user did not sleep long enough for a valid analysis.
- The phone was not correctly positioned or came loose during the night.

Recommended action: repeat the recording under proper conditions, ensuring the device is correctly placed before sleep.

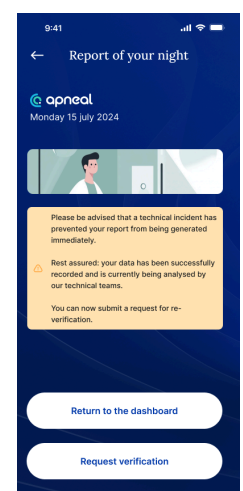


Case 2 — Technical incident

In this case, the report status will appear as "Technical error."

A temporary technical error has prevented the report from being generated immediately. The recorded data have been securely saved and are being reviewed by Apneal's technical team.

You can submit a **verification request** directly from the interface. Once the issue is resolved, the validated report will be made available in the dashboard.



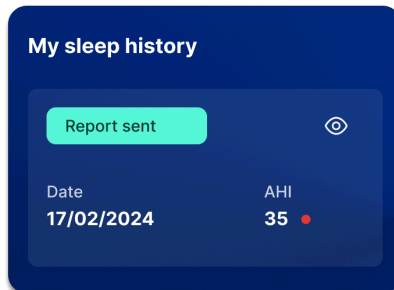
In both cases, you can safely return to the dashboard at any time. No health data is lost, and the application will guide you through the appropriate next steps to ensure data reliability and service continuity.



If the report **has not been generated**, you will need to **repeat your sleep study**.

4.8 Receive and display your analysis results

The application will provide you with an analysis of the signals recorded during your sleep, including information on sleep quality, such as the Apnea-Hypopnea Index (AHI), movements, position, heart rate, and snoring.

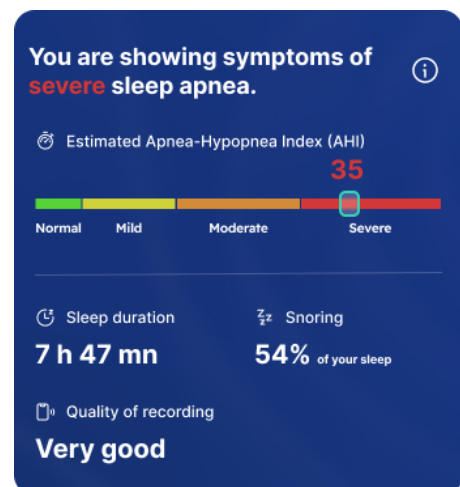


Once the report has been generated, you'll be **notified**. Your dashboard will display a summary card highlighting essential information from your sleep session, including report status, recording date, and the detected Apnea-Hypopnea Index (AHI). Clicking the eye icon will grant access to the complete sleep report.

The analysis findings are presented as a sleep report, offering a detailed overview of your nighttime sleep, including:

Sleep apnea symptoms observed during sleep

- Apnea Hypopnea Index (AHI)
 - Normal ● (Green) or
 - Mild ● (Yellow) or
 - Moderate ● (Orange) or
 - Severe ● (Red)
- Total sleep duration = effective sleep time (sleep onset → final awakening, excluding intermediate awakenings)
- Percentage of recording time during which snoring was detected
- Signal quality
 - Very Good or
 - Good or
 - Moderate or
 - Bad



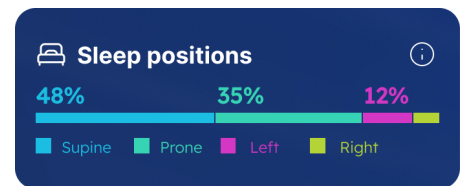
This score indicates the quality of the physiological data collected (airflow, position, snoring, heart rate, etc), not the quality of your sleep. A low score may be linked to a poorly positioned phone or a disturbed signal.



Sleep position

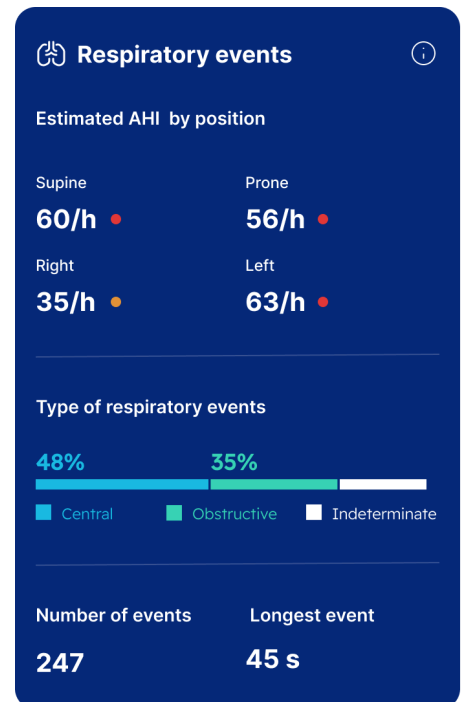
Distribution of sleep time by posture:

- Prone,
- Supine,
- Right side,
- Left side



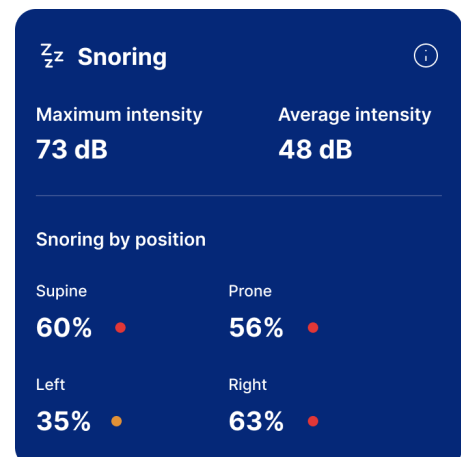
Respiratory events

- Respiratory events by position: estimated events index (events/hour) for each position
- Breakdown by type (Central / Obstructive / Unknown)
 - Central: absence of neural drive (e.g. central apneas)
 - Obstructive: airway obstruction despite respiratory effort
 - Unknown: inability to define the type of respiratory events
- Total number of respiratory events observed (sum of all events detected during the night)
- Duration of the longest event (in seconds)



Snoring

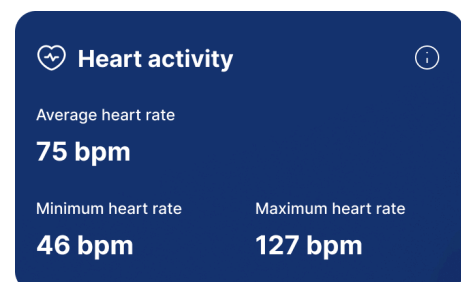
- Sound intensity
 - Average (dB)
 - Maximum (dB)
- Snoring by position (percentage of snoring time per posture, with color index - as defined for AHI section):
 - Supine
 - Prone
 - Left
 - Right



Cardiac activity

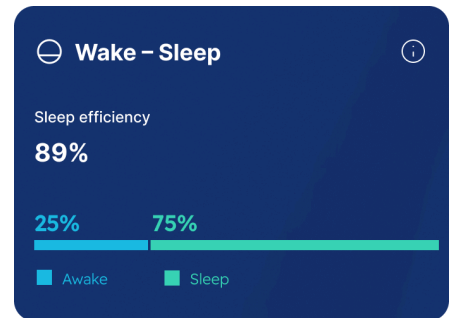
Heart rate

- Average (bpm)
- Maximum (bpm)
- Minimum (bpm)



Sleep stages

- Sleep efficiency (ratio of effective sleep time to total recording time)
- Proportion of the night spent asleep versus awake.

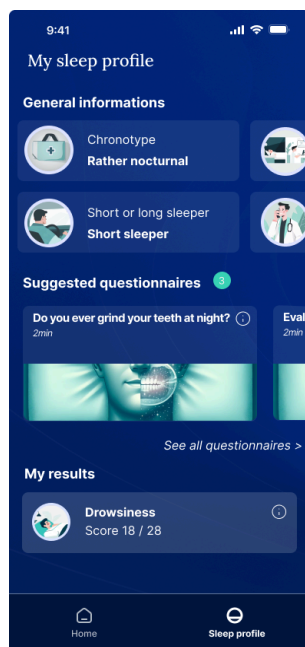


You can download your report in PDF format by clicking on the 'Advanced Report' button at the bottom of the 'Your Night Report' page.

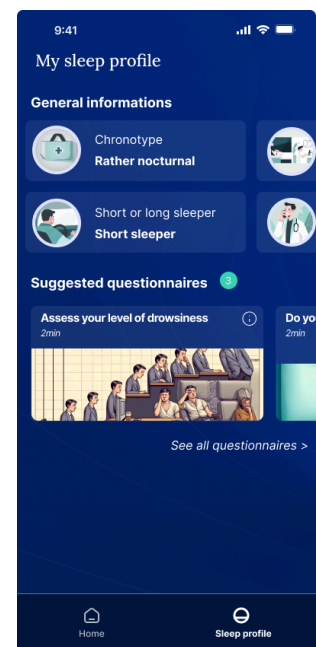
4.9 Other information

4.9.1 Sleeping profile

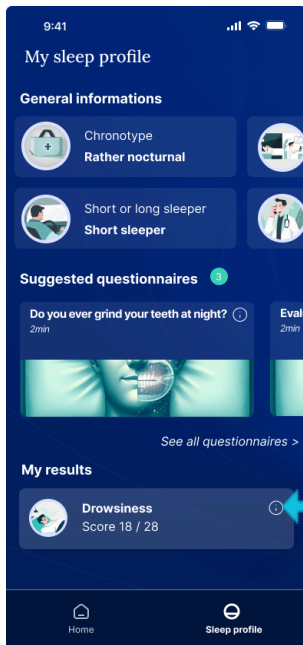
You can access your **"Sleep Profile"** section to view a summary of your general information collected during the onboarding questionnaires. You can also complete additional questionnaires to further refine your sleep profile analysis and enjoy a more personalized experience.



After completing any additional sleep questionnaires, your results will be available in the **"Results"** section.



4.9.2 Learn more about your health

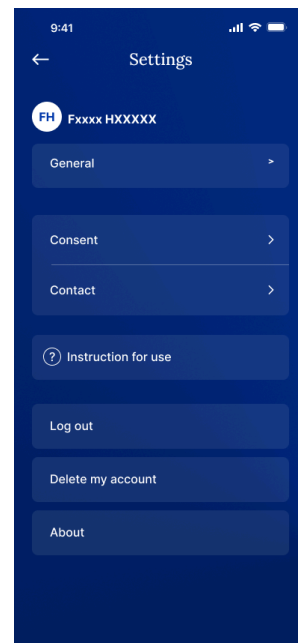
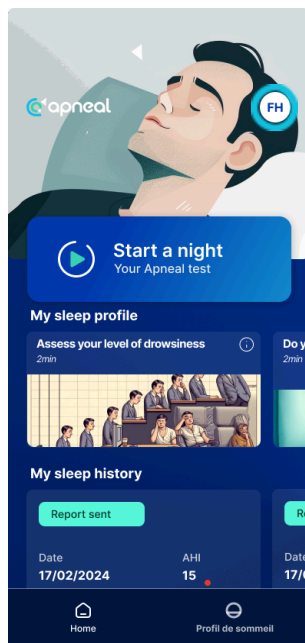


Want to know more about the questionnaires? Click the ⓘ :

- Understand what each questionnaire measures and how it works.
- Get guidance on what to do in specific situations, such as excessive daytime sleepiness.
- View your answers in detail.
- Retake the tests anytime you like.

4.10 Setting

Access the application settings by tapping the circle containing your initials, located at the top right of the home page.





4.10.1 General

To edit your personal information (name, contact, date of birth, weight, height, sex).

4.10.2 Consent

You can withdraw your consent at any time from there.



If you withdraw your consent to the '*Privacy policy*' or '*Terms of use*', you will be automatically logged out. To access the application again, you will need to provide your consent again.

4.10.3 Contact

You can contact the Apneal team directly from the 'Contact' screen to ask your questions or get help quickly.

4.10.4 User manual

You can access the user manual by clicking on the "User Guide" option. This allows you to quickly view instructions and learn how to use the app's features.

4.10.5 Log-out

You can log out simply by clicking on the "Log out" button. You will be logged out immediately.

4.10.6 Delete account

You can request to delete your account.



Once confirmed, all your personal data will be permanently removed, and you will no longer have access to the application.

4.10.7 About

Access the device's legal notices and regulatory labeling.

4.11 Patient portal

A web-based Patient Portal is available for you. It gives you access to additional features related to your account management and sleep diagnostic process.

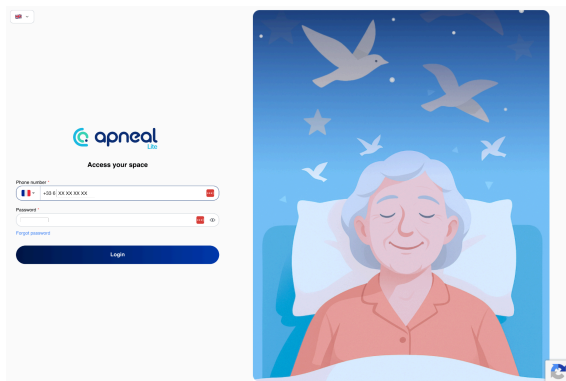
4.11.1 Payment process



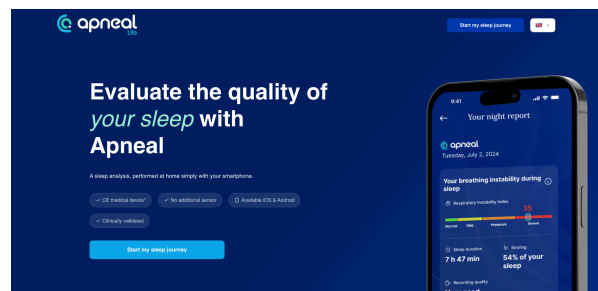
When you click the link in your invitation email or SMS, you will be taken to a login page where your phone number is prefilled for quick authentication.

After logging in, you will see a page introducing Apneal and our diagnostic solution. Clicking the “Start my sleep journey” button takes you to the payment page.

Once your payment is complete, a confirmation page will display your next steps.



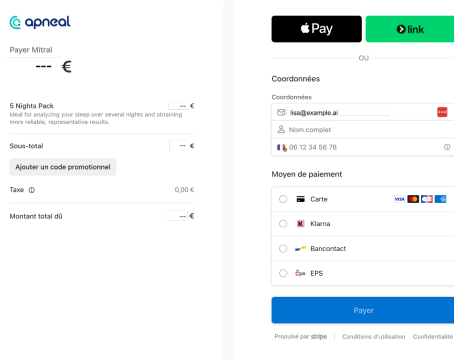
1



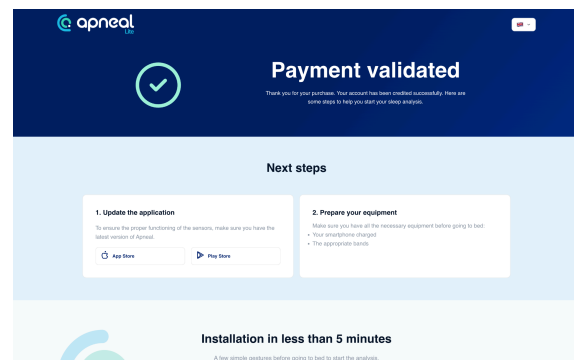
Why use Apneal?

A home solution to better understand your nights and get the keys to improve your sleep.

2



3



4



Payment Failure

Payment processing is handled securely by Stripe. If a transaction fails, the block originates from your financial institution, not the application. Please contact your bank directly to authorize the transaction, or use a different payment method.

4.11.2 Post night appointment

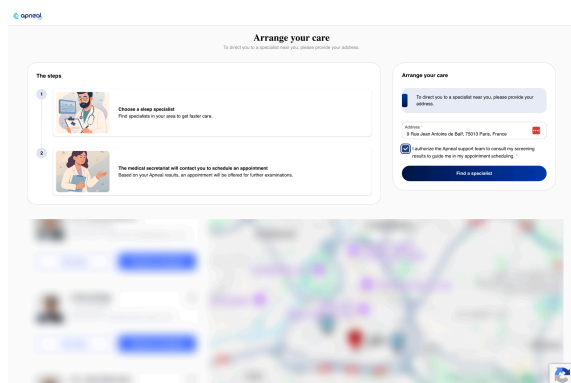
Depending on your care pathway, you may be referred to a specialist after your first night. If this applies to you, you will receive an email once your first-night recording is complete to help you continue your care.

By clicking the link in the email, you will be redirected to the Patient Portal to schedule an appointment with a specialist.

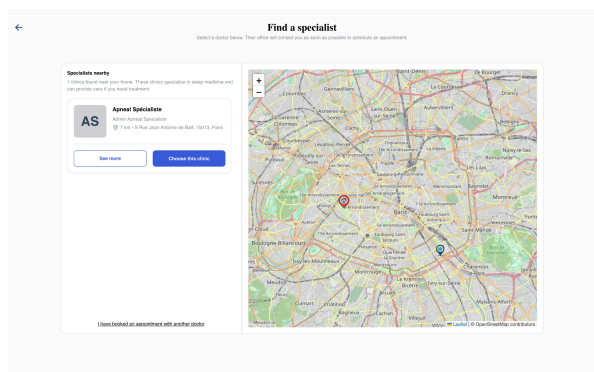
After logging in, a map appears: enter your address to find nearby specialists. The map view allows you to navigate and explore available specialists in the surrounding area. A list of clinics is also displayed on the interface's side. You can click **"See more"** for additional details about each clinic.

Once you make your choice, click **"Choose this clinic"**. Your appointment request is submitted, and the clinic is pinned on your map. The clinic's administrative team will then contact you directly to schedule your appointment.

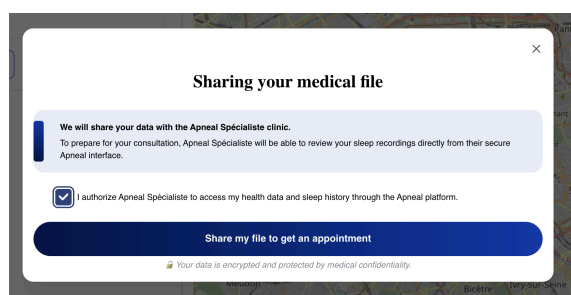
If you change your mind, you can always cancel your request by clicking **"Cancel my request"** on the platform.



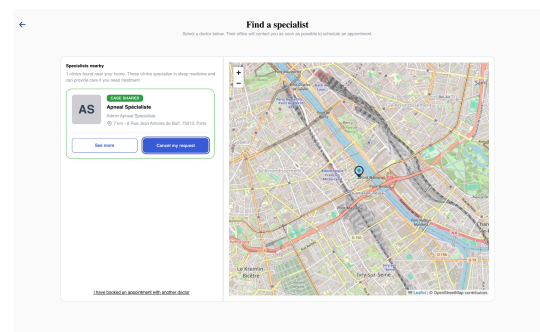
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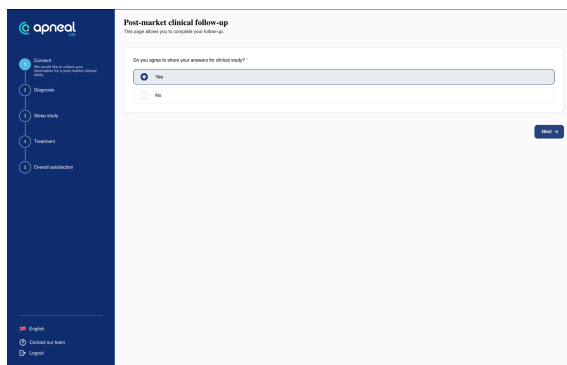
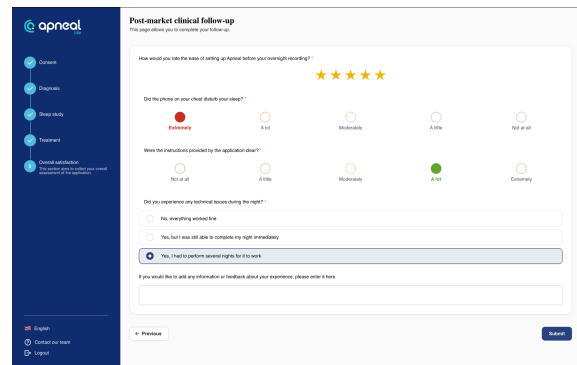
4.11.3 Post market clinical follow-up - PMCF

Approximately six months after your sleep test, we will email you a link to a follow-up questionnaire in the Patient Portal. This helps us improve our device and understand your care pathway.

When you log in, you will be asked for your consent:

- **If you consent:** You will answer a series of questions about your care journey and subsequent treatment.
- **If you decline:** You will only be asked to complete a very short survey about your general experience with our solution.

After submitting your answers, you will see a confirmation screen. No further action is required from you."

5. Maintenance

5.1 Cleaning

After use, some adhesive residue may remain on your phone's surface.

To remove it, we advise you to:

1. Switch off the device, then remove the protective shell
2. Soften the glue with a lukewarm breath.
3. Apply a soft cloth with a bit of isopropyl alcohol (70-90%), or vegetable oil (coconut oil) or a cloth slightly dampened with washing-up liquid.



Do NOT use water, sprays, or submerge your smartphone to clean it. Doing so can damage the device, affect recordings, detach adhesive accessories, and create a risk of electric shock.



Absolutely avoid the use of methods too aggressive for the plastic or screen:

- Acetone or nail varnish remover: too aggressive for the plastic or screen.
- Abrasive products: scrubbing sponges,
- Too much moisture: don't let liquid run into ports or buttons.

5.2 Technical maintenance recommendations

5.2.1 Software update

The application may be updated regularly to correct bugs, improve performance or add new features.

- By default, updates are automatic if this option is enabled in your phone's Google Play Store or Apple App Store.
- You can disable automatic updates in your smartphone's settings. In this case, it will need to be checked manually for new versions.

It is recommended that you keep the application up to date to ensure that it runs smoothly and securely.



Tap Start Night. If your app needs an update, you'll see a message, and you won't be able to continue. Tap Update to open the store and install the latest version.

5.2.2 Smartphone maintenance



Warning: The Apneal application runs on your personal smartphone. This smartphone is not a medical device. As the user, it is your responsibility to ensure that it is properly maintained, meaning:

- the operating system is up to date,
- the device is in good physical working condition (screen, sensors, battery, connectors),
- it is protected (with a password, etc.),
- and storage space is properly managed.

Any malfunction or damage to the smartphone may affect the proper functioning of the Apneal device.

5.3 Decommissioning and disposal

5.3.1 Uninstall the software

For more information on managing your data, please refer to the privacy policy, which is accessible from the application settings.

5.3.1.1 On iPhone (iOS)

- **Tap and hold** the app icon on your home screen.
- When a menu appears or the icons start to wiggle, select **"Remove App"** or tap the **minus sign (-)**.
- Confirm by choosing **"Delete App"** to permanently remove it.

Alternatively, you can go to **Settings > General > iPhone Storage** then, select the app, and tap **Delete App**.

5.3.1.2 On Android

- **Tap and hold** the app icon on your home screen or app drawer.
- Drag it to the **"Uninstall"** option or tap **"Uninstall"** from the pop-up menu.
- Confirm the action.

Alternatively, go to **Settings > Apps**, find the app in the list, tap it, and select **Uninstall**.



Uninstalling the app does not delete all user data.

Some data may be saved on the app's servers and can be recovered if you reinstall the app and log back into your account. For more information about how we manage your data, please consult our privacy policy. You can access it in the application settings.

If you want to delete all your personal data permanently, you usually need to follow these steps:



1. **Open the app** before uninstalling it.
2. Go to the **settings** within the app.
3. Select the option "**Delete Account**"
4. Follow the instructions to permanently delete your account and data.
5. After confirming the deletion, you can then uninstall the app.

5.3.2 Consumables: adhesive and cohesive bands

To ensure proper disposal of the consumables used to perform your sleep test (*i.e.* adhesive and cohesive strips), please refer to the information provided by the original manufacturer.

6. Troubleshooting and error messages

Icon	Description	Message
    	Blocking conditions	Warning: Certain conditions apply to your overnight stay. Storage space less than 2 GB Recording your night can take up a lot of space, and Apneal needs 1 GB of available space. Don't worry, once the night is over, this space will be available again. The battery charge is less than 60%. To record a full night, Apneal needs at least 60% battery. Device compatibility issue: application version is outdated, or the device is not supported for recording.
   	Account deletion confirmation request	You will request account deletion. The Apneal team will get back to you to keep you informed. → Delete or Cancel Your request has been taken into account It will be effective within 14 days → I understand
	Are you sure you want to cancel your registration?	Once you have cancelled your registration, you will be redirected to the home page.
	make sure to be in good condition to do the recording	Optimize your recording • Ensure a calm and quiet sleeping environment. • Avoid sharing your room, as another sleeper may interfere with the recording. → Continue
	Further information	You can find this symbol throughout the application. It allows you to obtain useful additional information.

7.Symbols

Symbols	Description
	Manufacturer
	Indicates that the product is a medical device
	Signals a medium containing information about a unique device identifier (UDI)
	Catalog reference
	Serial number
	Instruction for Use Consult the use manual.
	Warning or precautions: Indicates that special precautions are required when using the device, or that, in the current situation, the user must exercise vigilance or take action to avoid undesirable consequences.
	Important recommendation or information
	European CE marking indicating the conformity of the device to the European regulatory requirements related to medical devices according to (EU) 2017/745 The number below indicates the Notified Bodies issuing the CE certificate.
	Airplane mode
	Wifi mode
	Symbols indicating the device status: available storage space, battery level, and signal quality.
	Action buttons used in the application to access other screens: recording flow, sleep profile, and night report.



8.Expected lifetime and end-of-support policy

8.1 Expected lifetime

The Apneal Pro is designed and validated for an **expected lifetime of two (2) years** from its initial release date.

This expected lifetime assumes that:

- the application is used on smartphones listed as compatible in the latest version of the IFU,
- the user installs all manufacturer-released updates,
- and the device hardware continues to meet the performance requirements defined in the technical specifications.

After the expected lifetime has been reached, the manufacturer **cannot guarantee full performance or continued compatibility** of the software with future hardware versions.

8.2 End-of-support policy

At the end of the expected lifetime or if the software is no longer maintained:

- The manufacturer will cease updates, compatibility testing, and user support.
- Users will be informed in advance through official communication channels (e.g., app notifications, website).
- Continued use of the application beyond this period is at the user's own risk, as accuracy and performance can no longer be assured.

9. Compliance with international standards and regulations

To ensure safety and efficiency, the device has been developed in compliance with the following* standards and regulations

Designation	Name	Applied version
Regulation (EU) 2017/745	Regulation of the European parliament and the council of 5 April 2017 concerning medical devices (Medical Device Regulation)	5 April 2017
Regulation (EU) 2021/2226	Rules the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	14 December 2021
EN ISO 13485	Medical devices – Quality management systems requirements for regulatory purposes (ISO 13485:2016)	2016/A11:2021
EN ISO 14971	Medical devices – Application of risk management to medical devices (ISO 14971:2019)	2019/A11:2021
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015/Amd 1:2020
EN 62304	Medical device software – Software life cycle processes (IEC 62304)	2006/A1:2015
EN 82304-1	Medical device software – General requirements for product safety (IEC 82304-1)	2016
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2021)	2021

* An exhaustive list of standards and collaterals is available on demand.